

June 11, 2007

William D. Baker
Director
Julian F. Keith Alcohol and Drug Abuse Treatment
Center
201 Tabernacle Road
Black Mountain, NC 28711

Joint Commission ID #: 3377

Accreditation Activity: Unannounced Full

Event

Accreditation Activity Completed: 6/8/2007

Dear Mr. Baker:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

With that goal in mind, your organization received Requirement(s) for Improvement during its recent survey. These requirements have been summarized in the Accreditation Report provided by the survey team that visited your organization.

Please be assured that once your organization's Accreditation Report is available, the Joint Commission will keep the report confidential, except as required by law. To ensure that the Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Please visit <u>Quality Check®</u> on the Joint Commission web site for updated information related to your accreditation decision.

Sincerely,

Linda S. Murphy-Knoll

Interim Executive Vice President

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Division of Accreditation and Certification Operations



Julian F. Keith Alcohol and Drug Abuse Treatment Center 201 Tabernacle Road Black Mountain, NC 28711

Organization Identification Number: 3377

Date(s) of Survey: 6/8/2007 - 6/8/2007

PROGRAM(S)

SURVEYOR(S)

Laboratory Accreditation Program

Diane W. Miller, MT

Executive Summary

As a result of the accreditation activity conducted on the above date, your organization must submit Evidence of Standards Compliance (ESC) within 45 days from the day this report is posted to your organization's extranet site. If your organization does not make sufficient progress in the area(s) noted below, your accreditation may be negatively affected.

The results of this accreditation activity do not affect any other Requirement(s) for Improvement that may exist on your current accreditation decision.

Requirement(s) for Improvement

These are the Requirements for Improvement related to the Primary Priority Focus Area:

Analytic Procedures

Standard:

LD.2.110

Program:

LAB

Standard Text:

The laboratory director is responsible for maintaining any necessary quality control

programs.

Secondary Priority Focus Area(s):

Quality Improvement Expertise/Activities

Element(s) of Performance

Scoring Category: B

5. The laboratory director reviews quality control and proficiency testing data.

Surveyor Findings

EP 5

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

There was no documentation that the laboratory director had reviewed the proficiency testing data for the last six events of proficiency testing starting with the second event 2005 through the first event 2007.

Standard:

QC.1.20

Program:

LAB

Standard Text:

Proficiency testing services used for specialty and subspecialty* equal or exceed applicable laws and regulations with respect to variety and frequency of testing and

satisfactory performance criteria.

*This includes the specialty of Microbiology, sub-specialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; specialty of Immunology, sub-specialties of Syphilis Serology and general Immunology; Specialty of Chemistry, sub-specialties of routine Chemistry, Endocrinology, and Toxicology; Specialty of Hematology; Specialty of Pathology, sub-specialty of Cytology (limited to gynecologic examinations); and specialty of Immunohematology (ABO group and D (Rho) typing, unexpected antibody detection, compatibility testing, and antibody identification).

Secondary Priority Focus Area(s):

Quality Improvement Expertise/Activities

Element(s) of Performance

Scoring Category: C

7. For each specialty, subspecialty, analyte, or test, the laboratory's proficiency test performance is satisfactory. Note 1: The laboratory's proficiency test performance is satisfactory according to the following:

Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and D (RHo) typing and compatibility testing

Attaining a score of at least 100% for ABO group and D (RHo) typing or compatibility testing

Returning proficiency testing results to the proficiency testing provider within the timeframe specified by that provider (Note: Failure to return proficiency testing results to the proficiency testing provider within

Requirement(s) for Improvement

Standard:

QC.1.20

Program:

LAB

Standard Text:

Proficiency testing services used for specialty and subspecialty* equal or exceed applicable laws and regulations with respect to variety and frequency of testing and satisfactory performance criteria.

*This includes the specialty of Microbiology, sub-specialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; specialty of Immunology, sub-specialties of Syphilis Serology and general Immunology; Specialty of Chemistry, sub-specialties of routine Chemistry, Endocrinology, and Toxicology; Specialty of Hematology; Specialty of Pathology, sub-specialty of Cytology (limited to gynecologic examinations); and specialty of Immunohematology (ABO group and D (Rho) typing, unexpected antibody detection, compatibility testing, and antibody identification).

Secondary Priority Focus Area(s):

Quality Improvement Expertise/Activities

Element(s) of Performance

the timeframe specified by that provider results in a score of 0 for the testing event)

No omission of results on the proficiency testing form (Note: Omission of results could lead to a failure of attaining the score necessary for satisfactory performance (see bullets 1 and 2))

Participating in a proficiency testing event* (Note: Failure to participate in a proficiency testing event which results in a score of 0 for the testing event) Note 2: Most proficiency testing events with less than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QC.1.60 or non-CMS approved proficiency testing provided by the instrument manufacturer

*Consideration may be given to those laboratories failing to participate in a testing event only if the following occurs:

□œ Patient testing was suspended during the time frame allotted for testing

Surveyor Findings

EP 7

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

The laboratory had not participated in the proficiency testing event B 2005 for urine drug testing.

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

The laboratory had not participated in the proficiency testing event A 2006 for urine drug testing.

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

The laboratory's proficiency testing performance was not satisfactory for event A 2006 and event B 2005. These were urine drug proficiency testing that had no participation.

Standard:

QC.1.140

Program:

LAB

Standard Text:

The laboratory establishes and follows written guidelines for reagent and solution

labeling.

Requirement(s) for Improvement

Standard:

QC.1.140

Program:

LAB

Standard Text:

The laboratory establishes and follows written guidelines for reagent and solution

labeling.

Secondary Priority Focus Area(s):

N/A

Element(s) of Performance

Scoring Category: A

4. No reagent is used after its expiration date.

Surveyor Findings

EP 4

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

During a patient tracer at Women's Dorm, the high and low quality control vials were not labeled with the opened date. Therefore, it could not be determined if the control material was in working order.

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

During the tour of the laboratory, the surveyor retrieved a box of occult blood slides and developer that had expired as of January 2007.

These are the Requirements for Improvement related to the Primary Priority Focus Area:

Information Management

Standard:

HR.3.10

Program:

LAB

Standard Text:

Staff competence to perform job responsibilities is assessed, demonstrated, and

maintained.

Secondary Priority Focus Area(s):

N/A

Element(s) of Performance

Scoring Category: B

18. After the first year, each staff member's testing performance is evaluated and documented on an annual basis.

Surveyor Findings

EP 18

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

Annual competency documentation was not available for two staff members who performed the testing in the patient tracers.

Requirement(s) for Improvement

These are the Requirements for Improvement related to the Primary Priority Focus Area:

Organizational Structure

Standard:

QC.1.30

Program:

LAB

Standard Text:

The laboratory maintains a cumulative record of participation in a proficiency testing

program.

Secondary Priority Focus Area(s):

Information Management

Element(s) of Performance

Scoring Category: A

2. The laboratory documents the review of each report by the director or technical supervisor, even if testing events are successful.

Scoring Category: B

4. For each unacceptable result, there is a comprehensive investigation, and remedial action sufficient to address and correct the issues identified in the investigation.

Surveyor Findings

EP 2

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

There was no documentation of the reviews of each proficiency testing events from event B 2005 through event A 2007.

EP 4

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

For two unacceptable analytes in event C 2006, there had been no remedial action performed.

Supplemental Findings

These are the Supplemental Findings related to the Primary Priority Focus Area of:

Analytic Procedures

Standard:

QC.12.10

Program:

LAB

Standard Text:

The laboratory ensures the accuracy of serologic tests, including those for syphilis,

through the use of appropriate controls and tests for antigen reactivity.

Secondary Priority Focus Area(s)

Information Management

Element(s) of Performance

Scoring Category: C

6. The laboratory documents all controls, including the internal procedural controls.

Surveyor Findings

EP 6

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477

During a patient tracer for 2007, there was no documentation of the internal quality control for a pregnancy test.

Observed in laboratory at Julian F. Keith Alcohol and Drug Abuse Treatment Center site for CLIA # 34D0247477.

During a patient tracer for 2006, there was no documentation for the internal quality control for a pregnancy test.